Sue Bhadare, BSc (Hons)

Virginia, USA. Freelance Clinical Consultant

Profile: Successful expert in drug development with over 25 years of experience, specifically with plasma products and the FDA, specializing in clinical trial operations, regulatory strategy, protocol development and trial conduct with extensive FDA consulting and Pre-IND preparations and Orphan Drug approvals.

Clinical Trial Experience: Conduct of all phases of clinical trials (Phases I, II, III and IV) with experience in many therapeutic areas including Primary Immunodeficiency (PID), Alpha-1 Antitrypsin Deficiency (AATD), hemostasis in surgery (fibrin sealants), albumin therapy, Fresh Frozen Plasma (FFP) treatment, Plasminogen Deficiency, treatment with hyper immune immunoglobulins, Human Immunodeficiency Virus (HIV) infection, deficiencies in coagulation factors VIII (hemophilia A), IX (hemophilia B), VIIa, X, and XIII, von Willebrand Disease, Immune (Idiopathic) Thrombocytopenic Purpura (ITP), diabetic foot ulcers, gene therapy in Critical Leg Ischemia (CLI), influenza treatment, tinnitus and topical pain relief.

Well qualified to manage and select CROs for smaller companies who need an expert who can understand and manage a CRO on behalf of a Sponsor, troubleshooting and mitigating risks.

FDA Experience: Extensive experience in designing regulatory and clinical development strategies during early product development to prepare for Pre-IND meetings. Led multiple, successful Pre-IND meetings and End of Phase II Meetings at CBER, as well as IDE meetings at CDRH. Managed the filing of many successful INDs and BLAs. Responsible for clinical sections of multiple Regulatory submissions including Orphan Drug Designations and approvals.

Professional Experience

May 2002 – November 2012 **CROfessionals, LLC** **Warrenton, VA**

President

Founded and grew company from 4 employees in 2002 to 65+ employees at the peak of its success. Main focus was progressive research in niche therapeutic areas with limited patient populations. CRO was founded on being proactive in a niche therapeutic area and providing superior customer service to clients. Was entirely responsible for Business Development.

Clinical:

- Served as senior point of contact for Sponsor and CROfessionals in management of each study.
- Established and maintained Clinical Department budget and timeline requirements for entire pipeline.
- Served as Clinical Director, managing the Project Managers.

- Interfaced with regulatory authorities on behalf of the Sponsor to negotiate the design of planned studies.
- Supervised the development of presentations and made presentations to the FDA and other professional forums.
- Trained employees in key aspects of CROfessionals customer service and the plasma industry.

Regulatory and QA:

- Managed the Regulatory and QA departments.
- Active in the Quality Management System program including but not limited to authoring/editing of clinical SOPs.
- Designed aggressive and effective regulatory strategies for clients leading to successful licensure and substantial budgetary savings.
- Established scientific methods for the design and implementation of global clinical protocols, to meet the objectives of the Sponsor.
- Provided critical thinking in development of Pre-IND/IDE meeting packages for FDA and strategic advice to Sponsors in the development of presentations.

Business Responsibilities:

- Execution of the Business Model.
- Preparation of bids.
- Account and Resource Management
- Business Development.
- Client liaison and relationships.

Mar 1999 – May 2002 **OMRIX Biopharmaceuticals, Inc.** **Fairfax, VA**

Director, US Operations

- Managed and set up Omrix's entire clinical and regulatory operation in the US, consisting of a team of 12 employees.
- Managed clinical, regulatory, QA, and HR groups, as well as CRO's, and vendors.
- Ensured that the company's financial and quality targets were met.
- Conducted and managed two pivotal, fibrin sealant trials, leading successful BLA filing activities and gaining subsequent licensure within 18 months.
- Liaised with the FDA and handled all queries throughout the registration process.
- Initiated further studies to expand fibrin sealant licensure profile.
- Was responsible for the clinical development plan (CDP) and executed aggressive strategy to attract investment.
- Obtained approval for an IND and initiated a trial with an intravenous immunoglobulin (IVIG).
- Managed downsizing of the operation due to financial restraints and halting of all clinical activities.

Mar 1998 – Mar 1999 **OMRIX Biopharmaceuticals, Inc.** **Fairfax, VA**

Clinical Development Manager

- Closed out a failed study contracted to a CRO in the US.
- Successfully negotiated a new regulatory strategy with the FDA.
- Met with surgeons to select indications for implementing the Clinical Development Plan.

Sep 1996 – Mar 1998 **OMRIX Biopharmaceuticals, SA** **Brussels, Belgium**

Clinical Operations Manager

- Managed studies through CROs, with responsibility for protocol design, trial monitoring, data management and statistical reporting, and preparation of final study reports for submission to regulatory authorities.
- Completed five Phase III trials in Europe and Israel (leading to license approval in the EU), with fibrin sealant and hepatitis B hyperimmune immunoglobulin.
- Responsible for budget and total CRO management.

Oct 1995 – Sep 1996 **ClinTrials Research Ltd.** **Portugal**

Clinical Monitor

- Monitored a Phase III cardiovascular study in 17 centers.
- Responsible for full site management and monitoring.

Jun 1995 – Oct 1995 **Covance Ltd.** **United Kingdom**

Business Development Manager

- Provided business development and clinical resource coordination in the Phase II division.

May 1993 – Jun 1995 **Octapharma Ltd.** **United Kingdom**

Clinical Monitor

- Responsible for market research activities for a fibrin sealant.
- Set up clinical trials for a solvent-detergent, virus-inactivated fresh frozen plasma.
- Monitored trials of Factor VIII, fibrin sealant and immunoglobulin products.

July 1986 – May 1993

Sales Specialist roles selling specialty drugs direct to physicians and hospitals.

Bio Products Laboratory	**United Kingdom**
Baxter Healthcare	**United Kingdom**
Serono Laboratories	**United Kingdom**
Pharmax Ltd. (Forrest Labs)	**United Kingdom**

Jul 1981 – Jul 1986 **Boots Pharmaceuticals** **United Kingdom**

Laboratory Technician

- Responsible for day-to-day laboratory assays in hematology, toxicology and immunology pre-clinical testing laboratory.

Education

Sep 1988 – June 1992 **Nottingham Trent University** **Nottingham, England**

- Biological Sciences BSc (Hons)

Sep 1981 – June 1984 **Nottingham Trent University** **Nottingham, England**

- Hematology and Serology Diploma (1st)

Industry Training

HIPPA	CROfessionals, LLC	Aug 2007
Good Clinical Practice	CROfessionals, LLC	2007/2008/2009/2010/2011/2012

Professional Organizations

- Plasma Protein Therapeutics Association- PPTA
- Association of Clinical Research Professionals- ACRP
- Society of Quality Assurance- SQA